

REMARKS

Claims 1-8 and 16-19 are pending for examination with claim 1 being an independent claim. Claim 1 was amended to cancel non-elected subject matter. Claim 16 was amended to correct a typographical error. No new matter has been added.

Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1-8 and 16-19 under 35 U.S.C. §112, second paragraph, as not enabled. Applicant respectfully traverses the rejection.

The Examiner rejected the claims as not enabled for the preparation of compounds according to the invention where Y and Z are Nitrogen, the applicant would like to point out the fact that support for this disclosure can be found on page 8 of the specification, where in the lines 17 to 20 it is clearly stated:

“The compounds of formula (V) are known, commercially available, or they are prepared using methods analogous to those used to prepare known compounds...”

The compounds defined as (V) in this statement are the ones including also Y and Z = N (pyrimidine) or one substituent being N and the other CH (pyridine).

Furthermore the Examiner argues that “only compounds wherein the core is benzimidazole have been made.” (Office Action at page 3). This objection is, however, inaccurate in view of the examples 42, 43, 53, 54, 63, 64, 75, 86, 105, 106, 117, 127, 128, 140, 141, 195, 206, 207, 218 and many others. All the arguments cited on page 3 of the Office Action must therefore be considered not supported by corresponding evidence.

The Examiner deems the testing data to be “limited to a number of compounds not considered to be representative of all the possible compounds encompassed by the claims.” (Office Action at page 3). Applicant respectfully notes that the burden enunciated by the courts for adequate enablement is that Applicant’s specification must teach the person of skill in the art to make and/or use the claimed invention without undue experimentation. Applicant’s specification clearly does provide an adequate description of the claimed compounds, and of appropriate testing conditions and methods, such that one of ordinary skill in the art is enabled to make the compounds and test them for the noted activities. The testing that one of ordinary skill in the art would engage in is merely routine for the person of skill in this art, who should be considered highly skilled (Applicant disagrees that the level of skill in the art is any lower than that, as is implied by the Examiner on page 4 of the Office Action). Thus, any experimentation required would be routine, not undue, and therefore the claimed invention is fully enabled by the disclosure of Applicant’s specification. There is no requirement under the law that all claimed compounds be tested.

Regarding the rejection of claims 6-8 and 16-19, Applicant respectfully requests reconsideration. The quotation of the article of Vasikaran is in the Applicant’s opinion not correct: it appears that the arguments and the interpretation of the Examiner tend to exclude the cited statement “potent inhibitors of osteoclasts-mediated bone resorption are only useful in treating Paget’s disease.....” from the context of the article as a whole, which refers in any case to biphosphonates. This leads to an incorrect interpretation of the information contained in the Vasikaran article which, in fact, is erroneous and contradictory if compared with the commonly accepted teaching derivable from the literature (like in the JCI).

On the same basis, the observation regarding the prophylaxis which the claimed compounds are applied to should be considered incorrect. Prophylaxis and treatment are merely matters of administering therapeutics at a time prior to or after the appearance of disease symptoms, respectively. Regarding the Examiner’s statement in the sentence bridging pages 4 and 5, it should be quite clear that Applicant’s specification need not enable the skilled artisan in the identification of people who might benefit from the claimed treatments; such identification is certainly routine and well-known in the medical arts.

Accordingly, Applicant respectfully requests withdrawal of the rejections made under 35 U.S.C. § 112, first paragraph.

Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 1, 8 and 23 under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 6 also is discussed and therefore also is assumed to be rejected under this section.

(1) In re Wiggins, 179 USPQ 421, refers to an indefinite formulation of heterocyclic ring systems only when this terminology refers to “broad nomenclature” including a large class of compounds which are not restricted to the specific technical field of the disclosed application. In the instant case, however, the term “heterocyclic” has undergone a limitation by the definition of a “heterocyclic C₁₋₆ alkyl group” referred to the substituent R_s and R_t. This distinction, together with the restriction dependent on the field of invention and on the chemical and pharmaceutical properties of the molecule (embodied by the examples provided in the application), provides a precise and distinct meaning of the claimed molecules.

(2) The association of the disease with the over-activity of osteoclasts in mammals together with the administration of a compound according to formula (I) as defined in claim 1, appears in Applicant’s opinion clear enough to delineate and determine the scope of application of the subject matter defined here. The definitions of the claims should be normally interpreted by means of the disclosure as a whole, and in this case, claim 6 if read on the basis of the information deducible from the description of the inventions and of the examples refers to a specific scope.

(3) In analogy to what stated under point (2) above, the disclosure of the invention and the different embodiments provided in the specification give the unambiguous key of interpretation of what has been claimed under “substituted or unsubstituted”. These terms are clear to one of ordinary skill in the art, particularly in view of the disclosure in the specification.

Accordingly, Applicant respectfully requests withdrawal of the rejections made under 35 U.S.C. § 112, second paragraph.

Rejection Under 35 U.S.C. § 102

Claims 1-3 and 5 were rejected by the Examiner under 35 U.S.C. § 102(b) as anticipated by Downing et al. (WO 95/30659), by Barraclough et al. (Eur. J. Med. Chem., 1992) and by King et al. (J. Chem. Soc. Perkin Trans., 1988). Claims 1-3 were rejected by compounds having Beilstein RN 5988985, 6009580, 208984 and 282385. Applicant respectfully traverses the rejections.

None of the cited prior art explicitly teaches or defines the compounds of formula (I) of claim 1. The compounds provided by the prior art and the ones disclosed in the present application are in fact not overlapping.

Accordingly, Applicant respectfully requests withdrawal of the rejections made under 35 U.S.C. § 102.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 1-3 and 5 under 35 U.S.C. § 103 as unpatentable over Downing et al. (WO 95/30659). Applicant respectfully traverses the rejection.

For the evaluation of the nonobviousness of the present invention, the Examiner states that even with the structural differences between the molecules defined in the present application and the molecules described in the cited prior art, the person skilled in the art would have deduced in an obvious way the subject matter claimed by Applicant. It is respectfully submitted,

however, that such an interpretation contradicts the Examiner's statement on page 3 of the Office Action:

"This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence, one skilled in the art could not reasonably extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds...". (emphasis added)

On this basis it is now not clear why the same argument applied in the comparison between the compounds of the prior art and the compounds of the present invention having structural differences should not apply.

It is the Applicant's opinion that, on the same grounds, the claimed compositions should be considered not only novel but also inventive over the prior art.

In addition, the Examiner's citation of In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971) and Merck & Co. v. Biocraft Labs, 874 F.2d 804, 10 USPQ 1843 (Fed. Cir.), cert. denied, 493 U. S. 975 (1989) is not dispositive. In Merck, the claimed composition was used for the "identical" purpose taught by the prior art. 10 USPQ2d at 1846. In Susi, the court also stated that the claimed compounds and the prior art compounds were "to be used for the same purpose." 169 USPQ at 425. Such is not the case here, where the claimed compositions have a specific purpose and activity relevant to osteoclasts, whereas the cited prior art teaches compositions that are "useful as pharmaceutical agents." (Office Action at page 6). This lack of specificity in Downing is not analogous to the situation presented and decided in Merck and Susi. Therefore, for this additional reason, the teachings of Downing are not a sufficient basis for rejecting the claims as unpatentable for obviousness.

The Examiner states further that one of ordinary skill in the art would have been motivated to select the claimed compounds from the Downing compounds "since such compounds would have been suggested by the reference as a whole." Office Action at page 7.

Applicant respectfully disagrees that Downing provides any motivation to the person of skill in the art to select Applicant's claimed compounds, and further disagrees with the legal sufficiency of the motivation. The motivation provided by the Examiner is not sufficiently specific on which to base an obviousness rejection. Merely stating that the reference "as a whole" provides the motivation is not enough. In re Dembiczak, 50 USPQ2d 1614 (Fed. Cir. 1999).

Accordingly, Applicant respectfully requests withdrawal of the rejections made under 35 U.S.C. § 103.

CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this response, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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